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UNCLAS ZAGREB 002113

SIPDIS

SENSITIVE

STATE FOR USTR/LERRION
USDOC FOR 4232/ITA/MAC/EUR/MROGERS

E.O. 12958: N/A
TAGS: [KIPR](#) [ETRD](#) [PREL](#) [HR](#)
SUBJECT: CROATIA FINALLY PROVIDES DATA EXCLUSIVITY;
PIPELINE PROTECTION IN DOUBT

REF: A. ZAGREB 1836 AND PREVIOUS
[B](#). TELCOM ERRION/DETWILER 11/17/04

[1](#)1. (U) On December 3, the Croatian parliament passed an amendment to the Drug Law which provides data exclusivity (protection against other companies using clinical trial data provided to the government as a condition of marketing authorization). The protection lasts for six years after the drug is first registered in either Croatia or in any EU member country. While the language is not as strong as that originally sought in the 1998 bilateral MOU on Intellectual Property (there is usually a lag of several years between when a drug is first registered somewhere in the EU and in Croatia), local U.S. pharmaceutical representatives have voiced their satisfaction with the provision. The opposition in parliament unsuccessfully attacked the legislation, charging the government with ignoring the interests of the Croatian health system and Croatian pharmaceutical companies. The government defended the measure, citing obligations under the MOU and to the EU.

[1](#)2. (SBU) We understand from Ref B that the interagency group considering the initiation of exchange of dipnotes necessary to bring the MOU into effect has determined that the USG cannot currently meet all the requirements of the MOU, and therefore will not bring the MOU into effect. In the absence of a determination that the USG is willing to bring the MOU into force, the embassy is uncertain about the prospects for pursuing pipeline protection legislation, which would have provided our companies a "second chance" to patent drugs not currently protected. As we understand it, such a provision is not called for under TRIPS; our argument for it was based on the obligations of the MOU. If the USG is now doubtful about bringing the MOU into force, we will have difficulty pressing the GOC on that basis.
FRANK

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